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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/674,496	01/11/2001	Bernard Delobel	199463US/XPC	1391

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/674,496

Applicant(s)

DELOBEL ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 26 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 13,18-20 and 27-31 is/are pending in the application.
- 4a) Of the above claim(s) 31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 13,18-20 and 27-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed January 26, 2006 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 21, 2005 has been entered.

Claims 1-12, 14-17 and 21-26 are cancelled.

Claims 13 and 30 are currently amended.

Claim 31 is withdraw-currently amended.

Claims 13, 18-20 and 27-31 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

All previous objections and rejections not set forth below have been withdrawn.

### ***Claim Rejections - 35 USC § 112***

Claims 13 and 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record.

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Applicants' arguments filed October 21, 2005 have been fully considered but they are not persuasive.

Applicants maintain that the specification describes with particularity a conserved, cysteine-rich structural motif defined by formula I (SEQ ID NO: 1)  $X_1CX_2CX_3CX_4CX_5CX_6CX_7$  that exhibits insecticidal activity. Applicants also point out that the specification describes with particularity that this motif comprises 6 cysteine residues that are set apart by 7 polypeptide subsequences of a defined length and a defined composition (see page 3, lines 33 -38; page 4, lines 1-3), and that for each subsequence  $X_n$ , a defined set of amino acid residues is explicitly provided (see page 4, lines 4-38). (reply page 13)

Applicants additionally point out that the claims have been amended to further clarify the claimed polypeptides defined by formula I (SEQ ID NO:1) as "having insecticidal activity", and definitions for subsequences  $X_1$ - $X_7$  have also been added. Applicants further point out that since a representative set of polypeptides having insecticidal activity have been identified in a purification fraction containing 60% methanol, the solubility of the claimed polypeptides in 60% methanol is a relevant identifying characteristic, and this feature has also been added to Claims 13 and 31. Applicants also point out the sequence of a TP isoform (from pea) and the sequence of leginsulin (from soybean) were found to contain the conserved motif and to share 65% sequence identity, and Applicants thus maintain that the claims directed to a genus of polypeptides that could be isolated from different species of legume plants reasonably should include polypeptides having sufficient sequence variability so that distinct polypeptides such as TP, PA1b, and leginsulin would not be excluded from this genus

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defined by formula I (see Figure 7). Applicants also maintain that it is not unreasonable to include terms such as “having at least 60% identity with SEQ ID NO:6 (TP) and SEQ ID NO:7 (PA1b)” to add a reasonable range of sequence variability, since no part of the specification suggests any intention to limit the present invention to only the disclosed sequences. (reply page14)

Applicants additionally maintain that they have characterized the insecticidal activity conferred by the motif defined by formula I of the present invention and have identified at least three examples of such polypeptides having the recited properties. Furthermore, in Figure 4 of Example 1 of the specification, Applicants point out that mortality rates for oryzae weevils exposed to at least 9 different types of legumes are provided (see page 9, lines 27- 37), and maintain that the specification therefore unquestionably describes the genus of polypeptides utilized in the claimed methods and demonstrates Applicants' possession of the claimed invention. (reply page14)

The Examiner maintains that the specification does not describe a representative number of species of insecticidal proteins that meet the structural limitations of the claims, as the specification does not describe a representative number of polypeptides resulting from the claimed formula (SEQ ID NO: 1)  $X_1CX_2CX_3CX_4CX_5CX_6CX_7$  , because only a single insecticidal protein resulting from the claimed formula, the TP polypeptide obtained from pea, is described.

With respect to the set of polypeptides having insecticidal activity that have been identified in a pea purification fraction containing 60% methanol, the Examiner maintains that these peptides are not representative of the broad genus of peptides recited in the claims because these peptides are described at page 14 as isoforms of the TP polypeptide

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and as being identical in amino acid sequence to the TP polypeptide with respect to their first 10 N-terminal residues.

With respect to the structural similarities between the TP isoform from pea and the sequence of leginsulin from soybean, the Examiner maintains that the specification does not disclose a common functional activity (i.e. an insecticidal activity) for leginsulin from soybean.

With respect to the motif defined by formula I, the Examiner maintains that Applicants have not established that the motif defined by formula I confers the insecticidal activity of the TP polypeptide, as Applicants have only established that the TP polypeptide and its isoforms exhibit insecticidal activity.

With respect to Figure 4, the Examiner maintains that the mortality rates for oryzae weevils exposed to at least 9 different types of legumes do not describe the broad genus of peptides recited in the claims because the structure(s) of the legume agent(s) responsible for the mortality rates for oryzae weevils are not disclosed.

Claims 13, 18-20 and 27-30 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of protecting a plant from insects comprising treating the plant with a composition comprising a polypeptide having a sequence of the disclosed TP polypeptide, does not reasonably provide enablement for methods comprising treating the plant with other compositions comprising other polypeptides having other sequences. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make

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and/or use the invention commensurate in scope with these claims, for the reasons of record.

Applicants' arguments filed October 21, 2005 have been fully considered but they are not persuasive.

Applicants point out that the specification teaches how to screen plants in order to identify candidates that are sources for polypeptides having the claimed insecticidal activity and comprising a motif defined by formula I. Applicants point in particular to Figure 4 of Example 1 of the specification (see page 9, lines 27- 37) which provides mortality rates for oryzae weevils exposed to several types of legumes tested, and Applicants maintain that because all legumes tested were toxic against a sensitive strain of weevils but not a resistant strain, the same mechanism for causing insect toxicity is involved in all legumes tested. Applicants also point out that the toxicity assay provided in Example 1 can be applied to any plant of interest in order to determine the mortality curve or pattern for a given insect pest so that polypeptide candidates having insecticidal activity and comprising a motif defined by formula I (SEQ ID NO:1) of the present invention can be purified and subsequently sequenced. (reply pages 15-16)

Applicants also point out that a person skilled in the art could isolate a polypeptide conferring detected insecticidal activity by following the method disclosed in Example 2 which was used by Applicants to purify several isoforms of the TP polypeptide. (reply page 16)

Applicants additionally point to the alignment of the TP polypeptide amino acid sequence with the amino acid sequences of PA1b and leginsulin in Figure 7, and maintain that they are representative species of the genus of polypeptides recited in the claims. In

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this regard Applicants point in particular to their publication of the insecticidal properties of PA1b as shown in a reference submitted by Applicants in the last response as confirming that other polypeptides comprising the motif defined by formula I as having insecticidal activities (reference number 5 in Louis S. et al. (Molecular and biological screening for insect-toxic seed albumins from four legume species. Plant Science, 2004, Vol. 167, pages 705-714). Applicants also point in particular to the disclosure by others (Louis S. et al.) that polypeptides comprising the motif defined by formula I have insecticidal activities. (reply pages 16-17)

Applicants further point out that other polypeptides having insecticidal activity and comprising the conserved motif defined by formula 1 (SEQ ID NO:1) can be identified by searching various established sequence databases available at the time of the invention, as it is known how to perform database queries based a defined sequence of a conserved motif. (reply pages 17-18)

Applicants' comments with respect to the ability of one skilled in the art to isolate from plants or identify from sequence databases polypeptides that comprise a motif defined by formula I and then screen polypeptides so isolated or identified for insecticidal activity are inapposite to the outstanding rejection. The outstanding rejection was not predicated on a failure to disclose techniques that are within the abilities of one skilled in the art. The outstanding rejection was predicated on a failure to provide guidance with respect to which of the polypeptide sequence variants recited in the claims would have insecticidal activity and which would not, which guidance is necessary in light of the unpredictability of the sequence variants retaining the functional characteristics of the TP protein.



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With respect to Applicants' publication of the insecticidal properties of PA1b, the Examiner cannot comment specifically with respect to this publication as it has not been submitted; only the publication of Louis S. et al. was submitted by Applicants in the last response. Notwithstanding this the Examiner notes that the specification at page 13 discloses that the sequence of the TP protein and the sequence of PA1b pea albumin differ only by the replacement of a single amino acid residue, the valine residue at position 29 in the TP protein being replaced with an isoleucine in PA1b, as compared to the broadly defined genus of variant polypeptides recited in the claims.

With respect to the publication of Louis S. et al. itself, the Examiner reiterates that the disclosure of Louis S. et al. does not support the enablement of the claimed invention because Louis S. et al. did not obtain their results by following the disclosed methods. The Examiner also notes that Louis S. et al. is also silent with respect to the extent to which the polypeptides disclosed therein meet the structural and functional limitations of the polypeptides set forth in the rejected claims.

#### ***Remarks***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached on (571) 272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins  
Primary Examiner  
Art Unit 1638

CC

  
4/13/06